

REMARKS

The following remarks are offered in complete response to the Office Action dated March 12, 2007. Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 112, are respectfully requested in light of the following remarks.

Upon entry of the foregoing amendments, Claims 40-66, 77-116 and 137-145 will be in this application. Claims 1-39 have previously been cancelled without prejudice or disclaimer. Claims 40-66 and 97-106 have been withdrawn by the Examiner as being directed to a non-elected invention.

Claims 67-76 and 117-136 are cancelled without prejudice or disclaimer in this amendment.

Claims 77 and 107 have been amended to limit the administration to oral, to recite that there is an increase in the number of hairs per cm^2 of scalp and to replace "consisting essentially of" sample" with comprising. Support for these amendments is found at least in paragraphs [0051], [0028] and [0033] of the specification.

Claims 85-87, 95, 96, 115 and 116 have been amended to limit the administration to oral and to recite that there is and increase in the number of hairs per cm^2 of scalp. Support for these amendments is found at least in paragraphs [0051] and [0028] of the specification.

Claim 137-145 have been added. Claim 137 recites a method for increasing hair density by increasing the number of hairs per cm^2 of scalp through the administration of a composition comprising antioxidants vitamin A, vitamin C, vitamin E and also zinc and selenium salts, where a specific range of each of the

components is provided. Support for this claim is found at least in paragraphs [0033] and [0044] of the specification.

Claim 138, which depends from Claim 137, limits the amount of each listed component. Support for this claim is found at least in paragraph [0044] of the specification.

Claims 139 and 140, which depend from Claim 137, specifies that vitamin A is in the form of beta-carotene and provide a composition range for beta-carotene. Support for these claims is found at least in paragraph [0045] in the specification.

Claim 141 depends from Claim 137 and limits the amount of each listed component. Support for this claim is found at least in paragraph [0046] of the specification.

Claim 142 is analogous to Claim 77 with the inclusion of Claims 78-82. Support for this claim is found at least in paragraphs [0033], and [0048].

Claim 143 limits the zinc salt to zinc gluconate, zinc oxide, zinc sulfate or zinc chloride. Support for this claim is found at least in paragraph [0041] of the specification.

Claim 144 limits the selenium salt to sodium selenite, selenocysteine or selenoyeast. Support for this claim is found at least in paragraph [0041] of the specification.

Claim 145 limits the zinc salt to zinc sulfate and the selenium salt to sodium selenite. Support for this claim is found at least in paragraph [0041] of the specification.

No new matter has been added in making these amendments.

Specification

The Examiner has objected to the specification lacking reference back to the prior application. Applicants have amended paragraph [0001] to indicate this application is a divisional application of United States Patent Application 09/902,266, filed July 11, 2001, now abandoned. Applicants are grateful that the Examiner has noticed this informality and brought it to their attention.

Election/Restrictions

Applicants' acknowledge Examiner's decision to make final the election/restriction requirement based on the inventions being independent and distinct, each from the other. Applicants also point out that the Examiner has indicated that increasing hair density (Group III) is a distinct invention from promoting hair regrowth and/or retarding hair loss (group I). This distinction is important as the Examiner has used references teaching hair regrowth as relevant prior art.

35 U.S.C. §103(a) prior art rejections

1. Claims 77, 78, 83-88, 93-96, 107, 108 and 113-116 have been rejected under 35 U.S.C. §103(a) as unpatentable over Klett-Loch (US 6,013,279) in view of Schardt (DE 10021310 A1).

Applicants respectfully submit these claims are not obvious over Klett-Loch in view of Schardt and these claims are allowable.

To establish a *prima facie* case of obviousness, three basic criteria must be met. (MPEP 2143) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill

in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Klett-Loch discloses a composition containing vitamins, enzymes and amino acids that is useful for stimulating the growth of hair. The composition of Klett-Loch comprises vitamins A, C and E along with other vitamins, coenzyme Q10 and amino acids. Klett-Loch teaches that when the composition is administer orally, it is used to supplement an already topically applicable hair growth stimulant (see col. 2 lines 29-30). The use of the composition in accordance with the invention includes both an external and an internal treatment of the affected body cells. (see col. 2 lines 65-67). The components of the composition are given on a weight percentage. However, Klett-Loch also teaches that, in a preferred embodiment, a capsule has a weight of 480 mg and therefore the amount of these components can be determined.

<u>Component</u>	<u>Klett-Loch</u>		<u>Applicants</u>
	<u>quantity wt %</u>	<u>quantity (mg)</u>	<u>quantity (mg)</u>
vitamin A	1.25	6	0.1 - 3
vitamin C	15.61	74	50 - 240
vitamin E	2.5	12	10 - 60
zinc			10 - 40
selenium	up to 5% of a.i.	up to 8.34 mg	40 - 150 mcg

The amount of vitamin A in a capsule taught by Klett-Loch is 2 - 60 times the amount of vitamin A in applicants' invention while the amount of selenium taught by Klett-Loch is up to 55 times the maximum amount in applicants' invention. Klett-Loch discloses that the composition accelerates the multiphase, lengthy regrowth process, but does not disclose or suggest that the composition is useful for increasing hair density, which is defined in applicants' invention as increasing the number of hairs per cm² of scalp. The Examiner has indicated in the Office Action that the regrowth

of hair is a separate invention (see pages 2-4 of Office Action) and therefore the invention of Klett-Loch is distinct from that of the present invention.

Schardt discloses a hair lotion containing lactic acid, citric acid, panthenol or dexpanthenol, sodium selenite, potassium iodate, zinc sulfate, silicic acid and ascorbic acid, the remainder being distilled water (optionally mixed with alcohol). The hair lotion is useful in topically treating dandruff and alopecia. Schardt teaches that the use of the hair lotion according to the invention is to be used only outwardly. Therefore this composition is not relevant to the applicants' invention, which requires a composition for oral application. Schardt also does not suggest use of the lotion to increase the number of hairs per cm² of scalp.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There is no suggestion or motivation in Klett-Loch or Schardt to combine the references to obtain the applicants' invention. There is no suggestion or motivation in Klett-Loch or Schardt to combine an orally administered composition used for hair growth with a hair lotion used to control dandruff and alopecia to obtain the applicants' invention, which increases the number of hairs per cm² of scalp. In fact Schardt teaches away from combining the hair treatment with an oral treatment by stressing that the hair lotion according to the invention is to be used only outwardly. The Examiner alleges that one of ordinary skill in the art would have been motivated to add the composition taught by Schardt to the composition used in the method taught by Klett-Loch to provide the claimed invention because Schardt taught that compositions comprising zinc sulfate and sodium selenite were

useful in making pharmaceuticals having the beneficial functional effect of treating alopecia. Contrary to the Examiner position, it would not have been obvious for one skilled in the art to take a component from a topical application and add it to an oral composition. This is especially true because Schardt teaches away from the combination with an oral treatment by stressing that the hair lotion according to the invention is to be used only outwardly. Therefore, there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to obtain the invention of the instant application.

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. There is no reasonable expectation of success based on the teachings in Klett-Loch and Schardt that combining a composition that is used to supplement a topically applicable hair growth stimulant with a hair lotion used for controlling dandruff and alopecia would produce an orally applied composition that increases the number of hairs per cm² of scalp. In fact because Schardt teaches away from combining the hair treatment with an oral treatment by stressing that the hair lotion according to the invention is to be used only outwardly there would not be a reasonable expectation of success. Therefore, there is no reasonable expectation of success in combining the cited references to obtain applicants' invention.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Neither Klett-Loch nor Schardt teach or suggest the claim limitation of increasing the number of hairs per cm² of scalp. In addition, because Schardt teaches away from the combination of the hair lotion with an oral application by stressing that the hair lotion

according to the invention is to be used only outwardly, the presence of zinc in the material being applied is neither taught nor suggested. Therefore, the prior art references, either alone or combined do not teach or suggest all the claim limitations.

Applicants respectfully submit that the claims are not obvious over Klett-Loch in view of Schardt and the rejection should be withdrawn.

2. Claims 77-83, 87-94 and 113-116 have been rejected under 35 U.S.C. §103(a) as unpatentable over Klett-Loch (US 6,013,279) and Schardt (DE 10021310 A1) in view of Balch et al., Navarra et al. and Williams et al.

Applicants respectfully submit these claims are not obvious over Klett-Loch and Schardt in view of Balch et al., Navarra et al. and Williams et al. and these claims are allowable.

The teachings of Klett-Loch and Schardt have been previously discussed.

Balch et al. teaches the use of vitamins and minerals in nutritional healing and disclose the use of selenium and zinc. Balch et al. do not disclose the use of selenium to increase the density of hair, but rather teach that symptoms of excessively high levels of selenium include hair loss. Balch et al. disclose that a possible sign of zinc deficiency includes hair loss. However Balch et al. does not teach the use of zinc to increase the number of hairs per cm² of scalp.

Navarra et al. disclose the use of vitamins, minerals and supplements. Navarra et al. teach that hair loss is a possible sign of zinc deficiency, but does not teach the use of zinc to increase the number of hairs per cm² of scalp.

Williams et al. disclose a vitamin/mineral composition comprising, in relevant part, vitamins A, C, E and the minerals zinc and selenium. The amount of vitamins

A, C and E and selenium is far greater than amount of these items in the applicants' claims, as shown in the table below.

<u>Component</u>	<u>Williams</u>		<u>Applicants</u>
	<u>quantity (IU)</u>	<u>quantity (mg)</u>	<u>quantity (mg)</u>
vitamin A	33,000-40,000	9.9 - 12	0.1 - 3
vitamin C		4,000 - 5,000	50 - 240
vitamin E	600 TO 650	400 - 433	10 - 60
zinc		15 - 30	10 - 40
selenium		200 TO 250 mcg	40 - 150 mcg

Williams et al. teach that one of the distinguishing features of the composition are the high (as compared to U.S. RDA) amounts of all vitamins. Williams et al. does not suggest the use of their compositions for increasing the density of hair. In fact Williams et al. only discloses that vitamin A functions for the maintenance of healthy hair.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There is no suggestion or motivation in Klett-Loch, Schardt, Balch et al., Navarra et al. or Williams et al. to combine the references to obtain the applicants' invention which increases hair density by increasing the number of hairs per cm² of scalp. The Examiner alleges that one of ordinary skill in the art would have been motivated to add the ingredients taught by Balch et al., Navarra et al. and Williams et al. to the method taught by the combined teachings of Klett-Loch and Schardt to provide the claimed invention because the other claimed ingredients were known in the art for their beneficial effects, as evidenced by the teachings of Balch et al., Navarra et al. and Williams et al. Applicants submit that neither Balch et al., Navarra et al. nor Williams et al. overcome the deficiencies of

Klett-Loch and Schardt, as discussed above. Balch et al. do not disclose the use of selenium to increase the density of hair, but rather teach that symptoms of excessively high levels of selenium include hair loss. Based on the teachings of Balch et al., one skilled in the art would not be motivated to orally apply a composition comprising selenium, as this would only further increase the levels of selenium. The Examiner has not indicated that Navarra et al. either teaches or suggests the use of selenium to increase the density of hair and has not produced any portion of Navarra et al. related to selenium. There is no suggestion or motivation in Williams et al. to combine selenium and/or zinc with the invention of Klett-Loch to arrive at the applicants' invention. Williams et al. is silent on the use of selenium and zinc in having any effects on hair, and especially on increasing the number of hairs per cm² of scalp. Therefore, there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to obtain the invention of the instant application.

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. Applicants submit that neither Balch et al., Navarra et al. nor Williams et al. overcome the deficiencies of Klett-Loch and Schardt, as discussed above. Balch et al. do not disclose the use of selenium to increase the density of hair, but rather teach that symptoms of excessively high levels of selenium include hair loss. One skilled in the art, after learning of the teachings of Balch et al. would not expect that orally applying a composition comprising selenium would increase the density of hair, as this would only further increase the levels of selenium. One skilled in the art, after learning of the teachings of Navarra et al. and Williams et al.

would not reasonably expect to obtain the applicants invention because there is nothing in any of the references that would lead one to reasonably believe that such a composition would be effective in increasing the number of hairs per cm² of scalp. Therefore, there is no reasonable expectation of success in combining the cited references to obtain applicants' invention.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. As discussed above neither Klett-Loch nor Schardt teach or suggest the claim limitation of increasing the number of hairs per cm² of scalp. Neither Balch et al., Navarra et al. or Williams et al. overcome this deficiency. Balch et al. do not disclose the use of selenium to increase the density of hair, but rather teaches that symptoms of excessively high levels of selenium include hair loss. Therefore Balch et al. actually teach away from having a claim limitation in applicants invention. Navarra et al., as provided by the Examiner, is silent on the use of selenium. Williams et al. is silent on the use of selenium for any effects on hair. Therefore, it is only through hindsight reconstruction, which is not permitted, that a multi-vitamin and mineral supplement as taught by Cooper et al. would be combined with the teachings of Klett-Loch. (See MPEP 2141.01) Therefore, the prior art references, either alone or combined do not teach or suggest all the claim limitations.

Applicants respectfully submit that the claims are not obvious over Klett-Loch and Schardt in view of Balch et al., Navarra et al. and Williams et al. and the rejection should be withdrawn.

3. Claims 77, 78, 83, 84, 87, 88, 93, 107, 108, 113 and 114 have been rejected under 35 U.S.C. §103(a) as unpatentable over Klett-Loch (US 6,013,279) and Schardt (DE 10021310 A1) in view of Cooper et al. (US 6,299,896) and Okada (JP 04342516).

Applicants respectfully submit these claims are not obvious over Klett-Loch and Schardt in view of Cooper et al. and Okada and these claims are allowable.

The teachings of Klett-Loch and Schardt have been previously discussed.

Cooper et al. discloses a multi-vitamin and mineral supplement tailored to men and post-menopausal women, pre-menopausal women and athletes. The amount of vitamins A, C and E and selenium is far greater than amount of these materials in the applicants' claims, as shown in the table below.

<u>Component</u>	<u>Williams</u>		<u>Applicants</u>
	<u>quantity (IU)</u>	<u>quantity (mg)</u>	<u>quantity (mg)</u>
vitamin A	5,000-10,000	18 - 36	0.1 - 3
vitamin C		1,000 - 2,000	50 - 240
vitamin E	800 - 1200	360 - 540	10 - 60
zinc		15	10 - 40
selenium		100 - 200 mcg	40 - 150 mcg

Cooper et al. teaches the use of higher levels of selenium to fight the high level of free-radicals produced by athletes. (see column 8 lines 41-42) Cooper et al. does not suggest the use of the composition for increasing the density of hair by increasing the number of hairs per cm² of scalp.

Okada discloses a hair cosmetic containing selenium formed by blending a hair cosmetic with a selenium compound such that the hair cosmetic contains 0.0001-1.0 weight % of a selenium compound. Okada discloses that the selenium compound can be an organoselenium compound, such selenomethionine, selenocysteine or selenocystine, or an inorganic selenium compound, such as

sodium selenite, potassium selenite, sodium selenate or potassium selenate. Okada discloses the topical use of the hair cosmetic in suppressing yellowing of hair, maintaining natural color and gloss of hair. Okada does not suggest the use of the composition for increasing the density of hair.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. As discussed above, there is no suggestion or motivation to combine Klett-Loch and Schardt, especially since Schardt teaches away from combining his hair treatment with an oral treatment by stressing that the hair lotion according to the invention is to be used only outwardly. There is also no suggestion or motivation in either Cooper et al. or Okada to combine these references. One skilled in the art, upon learning of the teachings of Schardt that the hair lotion should only be used outwardly, would not be motivated to combine the hair treatment of Okada with an oral treatment of Klett-Loch. There is no suggestion or motivation in Klett-Loch or Cooper et al. to these references. Cooper cites the use of zinc for "proper formation of DNA and RNA and is needed for growth and sexual development of women". (see col. 2, lines 15-16) Cooper et al. does not teach that zinc or selenium has any affect on hair, especially to increase the number of hairs per cm² of scalp. Therefore, there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to obtain the invention of the instant application.

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. There is no reasonable expectation of success based on the teachings in Klett-Loch, Schardt, Cooper et al. and Okada that the combination of these references would produce a method that increases the number of hairs per cm² of scalp. As discussed previously, neither Klett-Loch nor Schardt provide any reasonable expectation of producing a method that increases the number of hairs per cm² of scalp. There is also no indication in Cooper et al. or Okada that combining the references would result in a regime or regime that increased the number of hairs per cm² of scalp. At most the cited prior art could be interpreted to teach slowing or reducing hair loss, which is different than increasing the number of hairs per cm². Therefore, there is no reasonable expectation of success in combining the cited references to obtain applicants' invention.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. As discussed above neither Klett-Loch nor Schardt teach or suggest the claim limitation of increasing the number of hairs per cm² of scalp. Neither Cooper et al. or Okada overcome this deficiency. In addition, one skilled in the art would also not consider combining Okada with Cooper et al. This is because Okada teaches a composition for application to the hair and Schardt teaches away from the combination of a hair lotion with an oral application by stressing that the hair lotion of his invention, which also contained selenium, is to be used only outwardly. With regards to Cooper et al, it is only through hindsight reconstruction, which is not permitted, that a multi-vitamin and mineral supplement as taught by Cooper et al. would be combined with the

teachings of Klett-Loch. (See MPEP 2141.01) Therefore, the prior art references, either alone or combined do not teach or suggest all the claim limitations.

Applicants respectfully submit that the claims are not obvious over Klett-Loch and Schardt in view of Cooper et al. and Okada. and the rejection should be withdrawn.

In view of the foregoing, it is believed that the record rejections cannot be maintained against the claims. Further, favorable action in the form of a Notice of Allowance is believed to be next in order and is earnestly solicited. In the event that any issues remain unresolved, the Examiner is asked to contact the undersigned so that a personal interview can be arranged.

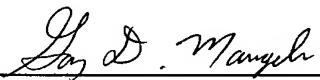
Reconsideration is respectfully requested.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By: _____


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